Application No.: 09/690,974

Office Action Dated: December 10, 2003

PATENT REPLY FILED UNDER EXPEDITED PROCEDURE PURSUANT TO 37 CFR § 1.116

This listing of claims will replace all prior versions, and listings, of claims in the application.

Listing of Claims:

Please amend claims 12, 22, 28, 29, 31 and cancel claims 1-11 and 34-36 as follows:

- 1. (Cancelled) A drug dosage form prepared by compression techniques comprising:
 - a thyroid hormone susceptible to moisture induced degradation, and
- at least one pharmaceutically acceptable excipient having equilibrium moisture, the drug dosage form prepared under conditions of low compression of up to 5,000 psi/g.
- 2. (Cancelled) The drug dosage form of claim 1 comprising a capsule.
- 3. (Cancelled) The drug dosage form of claim 1 comprising a capsule formed of hydroxypropyl methylcellulose.
- 4. (Cancelled) The drug dosage form of claim 1 wherein the compound is contained in solid form within a capsule.
- 5. (Cancelled) The drug dosage form of claim 1 wherein the form is subjected to no compression in excess of about 10,000 psi/g.
- 6. (Cancelled) The drug dosage form of claim 1 wherein the form is subjected to no compression in excess of about 5,000 psi/g.
- 7. (Cancelled) The drug dosage form of claim 1 wherein the form is subjected to no compression in excess of about 2,000 psi/g.

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8. (Cancelled) The drug dosage form of claim 1 wherein the excipient is hydroxypropyl methylcellulose, carboxymethyl cellulose, microcrystalline cellulose, amorphous silicon dioxide, magnesium stearate, starch, sodium starch glycolate, or a combination thereof.

9. (Cancelled) The drug dosage form of claim 1 wherein the excipient has a residual moisture content of less than about 10% by weight.

- 10. (Cancelled) The drug dosage form of claim 1 exhibiting improved stability to moisture-induced degradation of the compound as compared with a tabletted form of the compound.
- 11. (Cancelled) The drug dosage form of claim 1 comprising a unit dosage form.
- 12. (Currently Amended) A drug dosage form prepared by compression techniques comprising:

a substantially non-volatile, pharmaceutically acceptable oil, and

a compound susceptible to moisture-induced degradation admixed with

a substantially non-volatile, pharmaceutically acceptable oil, treated with the

substantially non-volatile, pharmaceutically acceptable oil to substantially waterproof the

compound susceptible to moisture-induced degradation;

the drug dosage form prepared by:

- (a) dispersing the compound susceptible to moisture-induced degradation in the substantially non-volatile, pharmaceutically acceptable oil; and
- (b) compacting the compound susceptible to moisture-induced degradation into dosage forms using under conditions of low compression pressures of up to 5,000 psi/g.
- 13. (Original) The drug dosage form of claim 12 wherein the oil is an animal or vegetable oil.

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14. (Original) The drug dosage form of claim 12 wherein said oil is olive, corn, peanut,

nut, soy, rapeseed, cottonseed, vitamin E, fish, or tallow-derived oil.

15. (Original) The drug dosage form of claim 12 wherein the oil is a mineral oil or

silicone oil.

16. (Original) The drug dosage form of claim 12 wherein the compound - oil admixture

is present within a capsule.

17. (Original) The drug dosage form of claim 12 wherein the compound - oil admixture

is present within a soft shell capsule.

18. (Original) The drug dosage form of claim 12 wherein the compound - oil admixture

is present within a specially sealed hard-shell capsule.

19. (Original) The drug dosage form of claim 12 wherein at least some of the compound

- oil admixture is adsorbed on a pharmaceutically acceptable excipient.

20. (Original) The drug dosage form of claim 12 wherein the excipient having the

compound - oil admixture adsorbed thereupon is within a capsule.

21. (Original) The drug dosage form of claim 12 wherein the excipient having the

compound - oil admixture adsorbed thereupon is within a tablet.

22. (Currently Amended) A drug dosage form prepared by compression techniques

comprising:

a pharmaceutically acceptable excipient admixed with a substantially non-volatile,

pharmaceutically acceptable oil; and

a compound susceptible to moisture-induced degradation, and

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a pharmaceutically acceptable excipient admixed with a substantially non volatile, pharmaceutically acceptable oil, treated with the pharmaceutically acceptable excipient to substantially waterproof the compound susceptible to moisture-induced degradation;

wherein the drug dosage form is prepared by:

(a). dispersing the compound susceptible to moisture-induced degradation in the

pharmaceutically acceptable excipient;

(b). compacting the compound susceptible to moisture-induced degradation into

dosage forms using under conditions of low compression pressures of up to 5,000 psi/g.

23. (Original) The drug dosage form of claim 22 wherein the oil is an animal or

vegetable oil.

24. (Original) The drug dosage form of claim 22 wherein said oil is olive, corn, peanut,

nut, soy, rapeseed, cottonseed, vitamin E, fish, or tallow-derived oil.

25. (Original) The drug dosage form of claim 22 wherein the oil is a mineral oil or

silicone oil.

26. (Original) The drug dosage form of claim 22 wherein the drug and the excipient - oil

admixture are present within a capsule.

27. (Original) The drug dosage form of claim 22 wherein the drug and the excipient - oil

admixture are present within a tablet.

28. (Currently Amended) A drug form prepared by compression techniques comprising:

a compound susceptible to moisture-induced degradation admixed treated with

a first pharmaceutically acceptable oil together with to substantially waterproof the

compound susceptible to moisture-induced degradation; and

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a pharmaceutically acceptable excipient admixed with a second

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pharmaceutically acceptable oil to substantially waterproof the pharmaceutically acceptable

excipient, wherein the first pharmaceutical acceptable oil is different from the second

pharmaceutically acceptable oil;

wherein the drug dosage form [[is]] prepared by:

(a). dispersing the compound susceptible to moisture-induced degradation

in the pharmaceutically acceptable excipient;

(b). compacting the compound susceptible to moisture-induced degradation

into dosage forms using under conditions of low compression pressures of up to 5,000 psi/g.

29. (Currently Amended) The drug dosage form of claim 28 wherein the first

pharmaceutically acceptable oil is an animal oil and the second pharmaceutically acceptable

oils are, independently, an animal or oil is a vegetable oil.

30. (Original) The drug dosage form of claim 28 wherein the first and the second

pharmaceutically acceptable oils are, independently, olive, corn, peanut, nut, soy, rapeseed,

cottonseed, vitamin E, fish, or tallow-derived oil.

31. (Currently Amended) The drug dosage form of claim 28 wherein the first

pharmaceutically acceptable oil is an mineral oil and the second pharmaceutically acceptable

oils are, independently, a mineral or oil is a silicone oil.

32. (Original) The drug dosage form of claim 28 wherein the compound - oil admixture

and the excipient - oil admixture are present within a capsule.

33. (Original) The drug dosage form of claim 28 wherein the compound - oil admixture

and the excipient - oil admixture are present within a tablet.

34. (Cancelled) A drug dosage form comprising:

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a compound susceptible to moisture induced degradation, and

at least one pharmaceutically acceptable hydrophobic powder,

wherein the drug dosage form is prepared under conditions of low compression of up to 5,000

psi/g.

35. (Cancelled) The drug dosage form of claim 34 wherein the hydrophobic powder is

triturated directly with the compound.

36. (Cancelled) The drug dosage form of claim 34 wherein the hydrophobic powder is

magnesium stearate.

37. (Withdrawn) A method for administering a compound susceptible to moisture-

induced degradation to a patient comprising providing a unit dose of the compound which has

not been processed employing high compression.

38. (Withdrawn) A method for administering a compound susceptible to moisture-

induced degradation to a patient comprising providing a unit dose of the compound admixed

with a substantially non-volatile, pharmaceutically acceptable oil.

39. (Withdrawn) The method of claim 38 wherein the compound - oil admixture is

present within a capsule.

40. (Withdrawn) The method of claim 38 wherein the compound - oil admixture is

adsorbed on a pharmaceutically acceptable excipient.

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- 41. (Withdrawn) A method for administering a compound susceptible to moisture-induced degradation to a patient comprising providing a unit dose of the compound and a pharmaceutically acceptable excipient admixed with a substantially non-volatile, pharmaceutically acceptable oil.
- 42. (Withdrawn) A method for administering a compound susceptible to moisture-induced degradation to a patient comprising providing a unit dose of the compound and at least one pharmaceutically acceptable hydrophobic powder.